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510(k) Summary
for the Adaptive Wedge

In accordance with 21 CFR 807.92 of the Federal Code of Regulations
the following 510(k) summary is submitted for the Adaptive Wedge

Date Prepared: March 2, 2011

1. **Submitter:**

Adaptive Specialty LLC
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Portland, OR 97210
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Contact Person:

J.D. Webb
The OrthoMedix Group, Inc.
1001 Oakwood Blvd
Round Rock, TX 78681
Telephone: 512-388-0199

2. **Trade name:** Adaptive Wedge
Common Name: Bone Wedge
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories.
Product Code: HRS
Class II

3. **Predicate or legally marketed devices which are substantially equivalent:**
BIOFOAM™ Bone Wedge (K073535 / K093950)

4. **Description of the device:**
The Adaptive Wedge has a distinct design to help facilitate bony integration once implanted. It has angular teeth to prevent backing out. It is offered in varying widths and thicknesses to accommodate a variety of small bone applications.

Materials:
PEEK Optima LT1 per ASTM F2026.
Titanium alloy per ASTM F136.

Function:
Used for angular correction of gaps and bony voids of small bones in the ankle and foot.

5. **Substantial equivalence claimed to predicate devices**
The Adaptive Wedge is substantially equivalent to the BIOFOAM™ Bone Wedges in terms of intended use, design, mechanical safety and performance.

6. **Intended Use:**
The Adaptive Wedge is intended to be used for internal bone fixation for small bone fractures or osteotomies in the ankle and foot such as:

- opening wedge osteotomies of Hallux Valgus
- Evans lengthening osteotomies
- Cotton osteotomy

This device is intended for use with ancillary fixation and is not intended for use in the spine.

7. Non-clinical Test Summary:

The following tests were conducted:

- Static compression testing
- Dynamic compression testing
- Determination of the coefficient of friction
- Determination of subsidence and debris generation during static and dynamic compression-shear testing

The results of this testing indicate that the Adaptive Wedge is equivalent to predicate devices.

8. Clinical Test Summary

No clinical studies were performed

9. Conclusions Nonclinical and Clinical

The conclusions drawn from the comparison between the devices demonstrate that the Adaptive Wedge is as safe, as effective, and performs as well as, or better, than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

MAR 12 2012

Adaptive Specialty LLC
% Mr. J.D. Webb
The OrthoMedix Group, Inc
1001 Oakwood Blvd
Round Rock, TX 78681

Re: K110662
Trade/Device Name: Adaptive Wedge
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Product Code: HRS
Dated: February 29th, 2012
Received: March 7th, 2012

Dear Mr. Webb:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K110662

Device Name: Adaptive Wedge

Indications for Use:

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Prescription Use X (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110662